

BILL ON THE MEASURES FOR THE PREVENTION AND CONTROL OF TUBERCULOSIS

Chapter I General provisions

Article 1. – This law regulates the general framework for the prevention and control of tuberculosis at individual level and at the level of the population, for the purposes of protecting human health.

Article 2.

(1) Tuberculosis is a priority public health issue in Romania, and its prevention and control represent strategic objectives of national interest.

(2) The Ministry of Health, as the central public health authority, shall be responsible for the coordination and initiation of all the measures required for the control of tuberculosis.

(3) For the purpose of bringing into effect the provisions of paragraph (2), the Ministry of Health, in collaboration with the other central and local public authorities, public and private institutions and NGOs shall prepare on a regular basis a national strategy to be adopted by decision of the Romanian Government.

(4) The objectives of the national tuberculosis control strategy shall be in line with the relevant strategic directions established by the World Health Organisation, the European Union and the applicable national legislation.

Article 3. – The Ministry of Health shall be responsible for the implementation of the National Tuberculosis Prevention, Surveillance and Control Programme.

Article 4. – The compliance with all the legal measures required for the control of tuberculosis shall represent an obligation of the central and public administration authorities, as well as of all legal and natural persons.

Article 5.

(1) In Romania, each person shall be entitled to free access to correct and complete medical, social and psychosocial support services for the control of tuberculosis.

(2) Within the meaning of this law, tuberculosis control services shall be classified as:

- a)** tuberculosis prevention services,
- b)** tuberculosis diagnosis services,
- c)** tuberculosis treatment services,
- d)** social and psychological support services for persons with tuberculosis.

Article 6. – Within the meaning of this law, the terms and expressions below shall be defined as follows:

- a)** treatment adherence – shall mean the strict observance by the patient of the recommended therapy, taking all the prescribed drugs, during the entire duration thereof;

- b)** suspect case/suspect – shall mean the person exhibiting signs or symptoms suggestive of tuberculosis before the diagnostic is confirmed;
- c)** tuberculosis contact – shall mean the person sitting in the vicinity of a contagious patient, at the distance required for conversation, for at least 4 hours;
- d)** strategic documents for the management of tuberculosis in Romania – shall mean all the documents prepared under the National Tuberculosis Prevention, Surveillance and Control Programme, namely implementing rules for the National Tuberculosis Prevention, Surveillance and Control Programme, clinical guidelines, the National Strategy for TB Control, as well as other regulations in force in the field;
- e)** closed-circuit pharmacy – shall mean the pharmacy ensuring the provision of drugs for human use to patients admitted to the hospitals that are part of the healthcare network of the Ministry of Health and of other ministries, institutions and associations that have their own healthcare network;
- f)** active identification of tuberculosis suspects and contacts – shall mean the identification of suspects by the primary healthcare services, school doctors, physicians providing employee healthcare services or specialist physicians providing care to groups that are considered at risk of tuberculosis, as well as sanitary mediators, community nurses and the specialised staff of the authorised social service providers;
- g)** group considered at risk of tuberculosis – shall mean persons from among tuberculosis patient contacts, people living in extreme poverty, homeless persons, persons living on welfare, HIV/AIDS-infected persons, drug users, the population in penitentiaries or other correctional institutions, persons chronically hospitalised in psychiatric facilities, persons with neoplasm, diabetes mellitus, chronic hepatitis or cirrhosis with B or C virus requiring specific treatments, persons undergoing immunosuppressive treatments for various conditions, organ transplant, treated collagenoses and other conditions treated with immunosuppressants, chronic alcoholics, the staff of healthcare facilities, workers exposed to toxic dust emissions/pneumoconiosis, construction site workers, persons living in common sleeping facilities, commuters, persons in social and health protection facilities, haemodialysis patients;
- h)** bacteriology laboratories – shall mean laboratories where the tuberculosis bacteriological exam is performed;
- i)** patient having completed the tuberculosis treatment – shall mean the patient who completed the full treatment prescribed but who does not meet the criteria to be assessed as cured or the localisation of the disease was extrapulmonary;
- j)** patient having completed the multidrug-resistant tuberculosis treatment –shall mean the patient who completed a full treatment scheme but who does not meet the criteria to be assessed as cured or as treatment failure because of the insufficient number of bacteriological results;
- k)** patient cured of tuberculosis – shall be the patient diagnosed with pulmonary tuberculosis, bacteriologically confirmed, who completed a full treatment scheme and whose culture is negative at the end of the treatment and at least one other previous check;

- l)** patient cured of multidrug-resistant tuberculosis – shall be the patient who completed a full treatment scheme in accordance with the protocol in force and who had at least 5 consecutive negative cultures collected at intervals of at least 30 days over the last 12 months of treatment;
- m)** prevention – shall mean any action that interrupts, stops or decreases the spreading of tuberculosis at individual level or in the population;
- n)** The National Tuberculosis Prevention, Surveillance and Control Programme – shall mean the national public health programme financed from the Ministry of Health budget;
- o)** treatment – shall mean all the drugs necessary for the treatment of tuberculosis, as referred to in the practice protocols for treatment prescription and monitoring issued by the Ministry of Health and recommended by the World Health Organisation;
- p)** directly observed treatment – shall mean the treatment administered to the tuberculosis patient under the direct observation of the medical staff, community nurse, social worker, sanitary mediator or other person identified in the community by the tuberculosis healthcare service where the patient is allocated, in collaboration with the local public social service;
- q)** tuberculosis – shall mean any form of infection with Mycobacterium tuberculosis, which manifests symptomatically, regardless of localisation, infectiousness or treatment sensitivity potential;
- r)** treatment resistant tuberculosis or multidrug-resistant tuberculosis – shall mean tuberculosis with microorganisms that are resistant to at least the treatment with isoniazid and rifampicin.

Chapter II

Tuberculosis prevention

Article 7.

- (1)** Tuberculosis prevention actions may target both the individual and the population, as a whole or in risk groups.
- (2)** The main tuberculosis prevention measures shall include, without limitation:
 - a)** the permanent information and education of the general population regarding the risk of tuberculosis, the disease transmission path, the main signs and symptoms, the available services, as well as the measures for the prevention and treatment of the infection;
 - b)** the education and counselling of tuberculosis patients regarding hygiene measures in order to prevent the infection from spreading;
 - c)** regular health checks and screening examinations, as appropriate, for the groups considered to be at risks, in accordance with the strategic documents for the management of tuberculosis in Romania;
 - d)** the rapid intervention in tuberculosis outbreaks, carried out in accordance with the strategic documents for the management of tuberculosis in Romania, with the

free examination of all persons with whom patients diagnosed with tuberculosis came into contact, and the determination of the prophylactic treatment for such contacts, where appropriate.

(3) For the purposes of bringing into effect the measures set out in paragraph (2), public institutions with responsibilities in the prevention, surveillance and control of tuberculosis shall collaborate on a permanent basis with national and international non-governmental organisations.

Chapter III

Tuberculosis diagnosis

Article 8. – Tuberculosis shall be diagnosed in accordance with the diagnostic algorithm and methods provided for in the strategic documents for the management of tuberculosis in Romania, in compliance with the principles and recommendations of the World Health Organisation.

Article 9. – Any person with symptoms of tuberculosis may refer directly to pulmonology dispensary, without having to obtain a referral from the family doctor in advance.

Article 10.

(1) All healthcare service providers must detect the signs and symptoms of tuberculosis in patients coming for consultation and refer the suspect cases to the territorial pulmonology dispensary in order for the diagnostic to be established in accordance with the provisions of the strategic documents for the management of tuberculosis in Romania.

(2) All healthcare service providers must notify in writing the territorial pulmonology dispensary in the event of a suspicion of tuberculosis in a person.

(3) In order to ensure the implementation of the active tuberculosis diagnosis measures, healthcare service providers shall collaborate with the authorised social service providers who carry out activities for the active identification of tuberculosis suspects and contacts.

Chapter IV

Tuberculosis treatment

Article 11.

(1) Persons diagnosed with tuberculosis shall be entitled to medical care of the highest quality the society can provide, without any discrimination on grounds of race, nationality, ethnicity, religion, social category, disadvantaged category, beliefs, age, gender or sexual orientation of the persons concerned.

(2) Tuberculosis shall be treated in the situations set out by the national practice protocols for the prescription, monitoring and refunding of the treatment prepared in accordance with the legal provisions, and in strict compliance with such protocols.

Article 12. – Medical assistance provided to persons diagnosed with tuberculosis shall be guaranteed by the state and based on the principles of respect for personal dignity, confidentiality, full gratuity and accessibility.

Article 13.

(1) The treatment of tuberculosis shall be provided free of charge to all persons diagnosed, in accordance with the form of the disease, and the drugs required for the treatment shall be made available through closed-circuit pharmacies.

(2) During the entire period of treatment administration, patients diagnosed with tuberculosis shall receive free of charge the drugs prescribed for the side effects caused by the anti-tuberculosis treatment.

Article 14.

(1) The medical treatment shall be provided to persons diagnosed with tuberculosis on a continuous basis, until they are cured.

(2) During the medical treatment, the patient diagnosed with tuberculosis shall be entitled to psychosocial support and counselling services.

Article 15.

(1) The anti- tuberculosis treatment of patients diagnosed with tuberculosis shall be administered under direct observation, in accordance with the recommendations of the World Health Organisation.

(2) Patients diagnosed with tuberculosis who are unable to travel to the territorial pulmonology dispensary shall benefit from residential directly observed treatment services provided by community nurses, sanitary mediators, social workers or specialised staff of the authorised social service provider.

Chapter V

Social protection measures for persons with tuberculosis

Article 16. – Persons diagnosed with tuberculosis who are insured under the public social health insurance system shall be entitled to leave from work and allowance for temporary work incapacitation, unconditioned by the stage of contribution to the social security system, throughout the treatment period, until they are cured.

Article 17.

(1) With a view to ensuring the treatment adherence of the patient diagnosed with tuberculosis, he or she shall be granted a monthly meal allowance throughout the outpatient treatment period.

(2) The amount of the allowance for tuberculosis patients shall be approved by Government decision, and the methodology and conditions for granting shall be approved by joint order of the Minister for Health and the Minister for Labour, Family, Social Protection and the Elderly.

Article 18.

The monthly meal allowance shall be provided from the state budget through the budget of the Ministry of Labour, Family, Social Protection and the Elderly and shall be paid on a monthly basis:

- a)** by postal money order;
- b)** to the personal account;
- c)** in another form of payment referred to in the application by the adult beneficiary or the child's legal representative;
- d)** to the special account opened for this purpose by the general social support and child protection directorates at county level or of the sectors of Bucharest, or to the authorised private body for the children entrusted or placed in the care of a public social institution or authorised private body.

Article 19.

(1) The monthly meal allowance shall be granted to the patient treated in outpatient facilities subject to the observance of the prescribed treatment, without discontinuation, for the month in question.

(2) In order to ensure the monthly meal allowances, the pulmonology dispensaries shall collaborate with the Ministry of Health, the Ministry of Public Finances and the agencies for payment and social inspection of the county or of the city of Bucharest, in order to calculate the amounts necessary to each patient undergoing outpatient treatment, throughout the treatment period in question.

Article 20.

(1) If the patient diagnosed with tuberculosis is not present for the treatment within the prescribed interval, the patient in question shall no longer be entitled to the monthly meal allowance.

(2) Patients diagnosed with tuberculosis who benefit from residential directly observed treatment administration shall receive the monthly allowance only provided they comply with the treatment prescribed, without discontinuation, for the month in question, and the provisions of Article 20(1) shall not apply in this case.

(3) The healthcare facilities shall notify the Ministry of Health and the county agencies for payment and social inspection with regard to the patients who abandoned the treatment.

Article 21. – The amount of the monthly meal allowance due to adults and children diagnosed with tuberculosis shall increase on the same date as the amount of meal allowances for collective consumption in public healthcare facilities.

Chapter VI

The duties of public institutions regarding the prevention and control of tuberculosis

Article 22. – The Ministry of Health shall manage the national pulmonology network consisting of pulmonology dispensaries, inpatient healthcare facilities, bacteriology laboratories, primary medical assistance with responsibilities in the

application and monitoring of the National Tuberculosis Prevention, Surveillance and Control Programme.

Article 23. – The “Prof. Dr. Marius Nasta” National Institute of Pulmonology in Bucharest shall be the methodological coordinator of the pulmonology network and the Central Management Unit of the National Tuberculosis Prevention, Surveillance and Control Programme.

Article 24.

(1) The pulmonology dispensaries in the Ministry of Health network shall ensure the diagnosis, treatment, registration, reporting and monitoring of tuberculosis cases, as well as the control of the transmission of the tuberculosis infection, by participating in the conduct of the epidemiological investigation.

(2) The pulmonology dispensaries shall collaborate with, and shall supervise the activity of, the family doctors and authorised social service providers carrying out activities in the detection of tuberculosis and the directly observed treatment, and in the conduct of the epidemiological investigation shall collaborate both with the family doctors, the public health directorate of the county in question, the local public social service, and the authorised social service providers carrying out activities in the field.

Article 25. – The Ministry of Justice, the Ministry of National Defence and the Ministry of Internal Affairs shall implement in their own healthcare networks and pulmonology facilities their duties regarding the National Tuberculosis Prevention, Surveillance and Control.

Article 26. – The staff of the public institutions and private bodies with responsibilities in the prevention, surveillance and control of tuberculosis must comply with the legal provisions regarding the confidentiality of persons diagnosed with tuberculosis.

Article 27. – All primary medical assistance providers must ensure the active identification of tuberculosis suspects and contacts and carry out the directly observed treatment of patients in accordance with the recommendations of the pulmonologist of the pulmonology network.

Article 28. – The county or local public authorities who have under administration inpatient healthcare facilities treating cases of treatment-resistant tuberculosis must establish, budget and maintain psychosocial support services for the patients concerned in the respective healthcare facilities.

Article 29. – The public social services subordinated to the county councils, the local councils of towns and cities, the local councils of the sectors of Bucharest and the Bucharest General Council shall ensure the provision of psychosocial support services to the patients diagnosed with tuberculosis in the territorial administrative unit in question.

Chapter VII

Public information regarding the risks of tuberculosis transmission

Article 30.

(1) The coordinating unit for the National Tuberculosis Prevention, Surveillance and Control Programme shall prepare on an annual basis a national public information plan regarding the risks of tuberculosis transmission and the measures for the prevention of tuberculosis infection, as well as regarding the counselling, care and treatment services offered to patients diagnosed with tuberculosis.

(2) The annual public information plan regarding the risks of tuberculosis transmission and the measures for the prevention of tuberculosis infection, as well as regarding the counselling, care and treatment services offered to patients diagnosed with tuberculosis shall be drawn up and implemented within 90 days from the entry into force of this law.

Article 31. – The patient having been declared cured with a complete treatment shall benefit free of charge from information and counselling services provided by the family doctor, with a view to preventing tuberculosis relapse.

Article 32. – Persons undergoing treatment for tuberculosis shall benefit from information, professional counselling and employment mediation, with a view to establishing work or service relations.

Article 33. – The Ministry of Health shall collaborate on a continuous basis with the Ministry of Education and the Ministry of Labour, Family, Social Protection and the Elderly in the preparation of the annual strategies for the information of the population with regard to the preventive measures that must be observed in education establishments and workplaces.

Chapter VIII

The funding of tuberculosis prevention, control and treatment measures

Article 34. – The actions taken for the prevention, control and treatment of tuberculosis shall be financed from the state budget, the single national social health insurance fund and from any other sources, in accordance with the law.

Article 35. – The Ministry of Health shall ensure the necessary funds for the complete, continuous and adequate financing of the National Tuberculosis Prevention, Surveillance and Control Programme.

Chapter IX

Final provisions

Article 36. – For the purposes of bringing into effect the measures for the control of tuberculosis in Romania, the central and local public authorities with responsibilities in the prevention, surveillance and control of tuberculosis shall collaborate on a permanent basis with all the healthcare service providers and with national and international non-governmental organisations.

Article 37.

(1) Within 3 months from the date of entry into force of this law, the amount of the meal allowance for adult and children patients diagnosed with tuberculosis shall be approved by Government Decision, and the methodology and conditions for the granting of the meal allowance to tuberculosis patients shall be approved by joint order of the Minister for Health and the Minister for Labour, Family, Social Protection and the Elderly.

(2) In order to ensure the funds necessary for the application of Article 17(1), the Ministry of Public Finances is hereby authorised to include, upon the proposal of the Ministry of Labour, Family, Social Protection and the Elderly, the amendments resulting from the application of the provisions of this law in the structure of the state budget and of the budget of the Ministry of Labour, Family, Social Protection and the Elderly.

(3) Starting on the date of entry into force of this law, but no later than 31 December 2016, the Ministry of Labour, Family, Social Protection and the Elderly, the Ministry of Health and the Ministry of Public Finances shall perform the appropriate amendments and supplementations of the legislative acts in force, in accordance with this law.

(4) Within 3 months from the date of entry into force of this law, the Ministry of Health, the Ministry of Labour, Family, Social Protection and the Elderly, the Ministry of Public Finances, the Ministry of Education, the Ministry of Justice, the Ministry of National Defence and the Ministry of Internal Affairs shall draw up the implementing rules for this law and shall submit them for approval by Government decision.

Article 38. – This law shall enter into force 3 days after its publication in the Official Gazette of Romania, Part I.

This law has been adopted by the Parliament of Romania in compliance with the provisions of Article 65(2) and Article 76(1) of the Constitution of Romania, republished.

PRESIDENT OF THE CHAMBER OF DEPUTIES

PRESIDENT OF THE SENATE

Bucharest

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